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Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

REF: Comments on PMN
Stakeholders Meeting
NIH 03.12.99
FdaDockets@bangate.fda.gov

Dear Sir/Madame:

Georgia-Pacific Corporation is a leading manufacturer of packaging and chemical products that by themselves or as components of other products can be considered "food contact substances." Therefore, we have a direct interest in the development of new food packaging product components and their safe and quick access to the market place. This is the major reason for our interest in this rulemaking process. Consequently, Georgia-Pacific Corporation, through the American Forest and Paper Association, has supported the proper funding of the Pre Market Notification (PMN) process as the vehicle to achieve the promise of the new statute.

The funding for PMN is now in a "special appropriation" status that requires annual legislative action. Congress wants to be sure that the implementation of the PMN meets the objectives sought in the Food and Drug Agency Modernization Act (FDAMA). Such assurance would help in seeking more adequate and stable funding as well as renewal funding as presently required. Any modification of the present funding system for the purposes of a more stable and adequate system or for its annual renewal will depend largely on the initial results of the PMN program once implemented. Congress will need to be assured that as implemented it meets the objectives sought in FDAMA. It is thus important that the implementation of the PMN program be a success. Our comments are intended to help make a successful implementation.

The modifications of section 309 of the FDAMA to section 409 of the Federal Food Drug and Cosmetic Act (FFDCA) were intended to accelerate the safe approval process of food contact substances or indirect additives. The new statute recognizes the different level of risk to public health between these substances and direct food additives. Although the standard of safety remains intact, as it should, the intent of the statute is clearly to have FDA develop a procedural mechanism that facilitates a rapid approval of notifications. The statute instructs the FDA to accelerate this approval process in a manner commensurate with the expected risk to public health. The above underlines the importance of new PMN regulations reflecting both innovations in the regulatory process as well as in the speedy availability of needed information.

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We wish to congratulate the Agency for holding a stakeholders meeting in preparation for the rulemaking process. The meeting provided a very informative exchange on the initial approaches envisioned by the Agency for PMN regulations. Advancing the three drafts on administrative, toxicological and chemistry procedures was very instructive although the available time was somewhat limited. Nevertheless, we were able to initiate a dialogue in some aspects of these documents. We encourage the Agency to continue this approach since it will generate the needed innovative features that will make the PMN program successful.

The following are comments on issues reflected in the three draft documents and on topics discussed in the March 12 meeting. These comments, due to the deadline of March 22, may not be inclusive enough. We have requested already, at the e-mail address, an extension of the deadline of March 22 suggesting April 12 as a reasonable new deadline.

1- The rule-making precess and the October 1999 goal -At the March 12 meeting there were comments about the possibility of having the new system in place by October of this year. It seems to Georgia-Pacific that this is a very ambitious goal for proper rule-making and the implementation of a needed innovative approach, which should include new informational resources. We urge the Agency to keep providing an opportunity for timely exchange of information with the stakeholders in the belief that it will be a sure way to generate the needed innovation.

2- The pre-submission meetings procedure and the threat of an extension of the 120-day challenge. The March 12 meeting provided a more realistic insight on the pre-submission meeting approach envisioned by the Agency. This approach and the desire of the Agency to interact with the submitter to facilitate proper submissions are commendable and welcomed. Nevertheless, it has to be tempered with resources, budgetary constraints and the intent of the FDAMA itself. A convergence of many submissions on limited resources could very easily extend the 120-day period into a second year or more. In fact, for the regulated community the “real world” period is whatever time the process takes from beginning to end. A transfer of part of the four-five year duration of an average petition into a pre-submission period will do little to achieve the objectives of the FDAMA or the continue support for the funding of the program.

In our opinion, the situation described above could be largely avoided by a series of measures as follows:

A thorough rule making-process with clear and detailed information on the expectations for proper submission;

An information system to help the submitter;

Sufficient resources to effectively manage both the pre-submission and post-submission reviews in a timely fashion.

3- Some information resources to facilitate the submission process and reduce the period of pre-submission meetings-

3.1- Allowable Dietary Intake (ADI)- At the March 12 meeting we brought to your attention the convenience and fairness of having available, for prompt delivery upon request, the ADIs

already in use by the Agency. We are keenly aware of the temporal factor attached to such an issuance. ADIs have been developed by the Agency during its normal petition review process for decades. The state of the art both in analytical and toxicological knowledge is an important factor. In principle, if the Agency keeps maintaining approval for old petitions, it is correctly assumed that they are adequate to insure the safety of the products approved as a result of their evaluation. Otherwise, the Agency would have them withdrawn as it is empowered to do. Our request on the matter is free of conditions. If the Agency wishes not to list old or replaced ADIs, that is its prerogative. Another approach suggested at the meeting was to provide information on the year that the ADI was developed. Such information, at least, will be helpful in alerting the submitter in its evaluation on the need to look further into the applicability of the published ADI to the notification in question. In either case, it will constitute a considerable help.

3.2- Cumulative exposure- The toxicological draft contemplates the need for the submitter to factor the cumulative exposure to the food contact substance. This apparently reasonable request needs to be examined from at least two standpoints. The first would be in the overall context of the safety margins factored in the whole assessment process. This cumulative approach should not result in an added overall resultant safety margin that will change the maintenance of the safety standard envisioned by the Act.

Another important and practical aspect is that there is a real need to provide as much information as possible about the different exposures of substances due to prior petitions, studies, etc. Also, the submitter needs to know as much as possible about the Agency's reviewing rationale for establishing probable consumption. In the present system of petition, the petitioner is required to supply information on the intended use of the substance in food. The same requirement is envisioned for the notification of a food contact substance.

Presently, for petitions, it is our understanding that the Agency reviewers select food intake data from the available databases. These databases, albeit some quality aspects already pointed out by the General Accounting Office, are generally based on specific food commodities disappearance or food intake surveys. Since the Agency reviewers make ad-hoc approaches and reasoned judgement, information on these is needed for the submitter of a notification.

In other words, in the present system of petition there is a shared task between the petitioner and the Agency. The new PMN leaves it entirely to the submitter of the notification but the Agency still remains the reviewer. Without providing the type of information indicated in the above, the notification approval process would be extremely lengthy and frustrating. This is an example of the innovative approaches that need to be developed and implemented to insure the achievement of the FDAMA goals.

4- More information on the rationale to exclude food contact substances from the pre-market notification program- The draft toxicological information document provided for the March 12 meeting indicates circumstances where the PMN is not applicable. Certainly, FDAMA, in its section 309 (b) gives the Secretary discretion to identify the circumstances under which a petition is required.

Two out of the three exceptions indicated in the draft toxicological document are based in the exceeding of a numerical threshold. It is desirable for the Agency to provide more detail information about the calculations and supporting data leading to the setting of those

numerical thresholds. Specifically, in the case of the ratio ADI/CEDI of 5. It is important not to increase the safety factors when not justified. If the safety factors built into the development of the ADI are equal to the uncertainty factor in the CEDI, then a factor of 5 becomes an added unjustifiable safety factor. We think more information is needed to either modify the ratio or to assure the stakeholders that there is not an unjustifiable increase in the safety margins.

The exception due to nature or timing of carcinogenicity studies appears too final. The submitter may not know if the Agency has or not reviewed the study or if it is in the process of doing so. Rather than closing the route for a petition, the Agency could instead request that all pertinent information on the study invoked be included in the submission. This is another example of making available important information to facilitate the notification procedure. The Agency could provide a listing of the studies it has reviewed. We frankly considered it impractical and prefer the request for submission of the supporting study as a practical one.

The Agency should also clarify the meaning of the reference to a calculated risk of 10 E-8 rather than the conventional 10 E-6 risk level. As described in the draft document, it could be interpreted as a final exception from the PMN. Finally, in the FCS subject of the petition, there may be detectable a carcinogen chemical but the FCS has itself not been shown to cause cancer. FDA has already taken a position on these cases according to the 6th Court Circuit decision on Scott v. FDA (1984). We would like to suggest the Agency makes clear its position on this regard. We are not expressing at this time a preference on the outcome of our suggestion.

5- The response to an approved PMN -As now envisioned, there will not be a written notice of approval on the basis that the absence of a rejection will mean an approval. There are situations that make such a simple approach problematic. The audit program of the Food Safety and Inspection Service (FSIS) of the USDA requires a justification of the complete chemical composition of the packaging item. Until such an audit takes place, the present procedure only requires the proper issuance of a guarantee letter with a traceable description of the packaging product and its intended range of use. Lack of a written approval will complicate and delay the completion of the auditing procedure.

In addition, it has been very helpful to the American exporter to provide, and have it accepted in other countries, the FDA approval of the food contact substances. The lack of a clear reference to such approval will create justifiable trade problems, not only abroad but also domestically. For these reasons we request that the Agency consider the issuance of approval letters as done in the case of TORS

6- On Confidentialitv. We would like to endorse the comments of Mr. Jerry Heckman on behalf of the Society of the Plastic Industries on the matter of confidentiality. We do not have more to add to them at this moment.

7- Finished Product versus Components - Section 309 (h)(6) defines food contact substance as any substance intended for use as a component of materials used in manufacturing, etc. Likewise, section 309 (h) (2) (C) indicates that a “food contact substance” means the substance is the subject of a notification which applies only to the manufacturer identified in the notification. It was not clear at the stakeholder meeting on March 12 how the Agency was interpreting the language of the statute in this regard.

There was a petition from the floor requesting a flexible interpretation of the language of (h)(6) so that a final product with different components would not require a notification process for each one of them. This is a logical observation that we think needs the attention of the Agency. A simpler example than the one given at the meeting could be obtained in reformulation or new applications. As a hypothetical example, section 175.300 provides the opportunity for formulations in which different components of resinous and polymeric resins can be reformulated in different ways, and requires a notification for the specific new formula. For example, epoxy resins, their catalysts (DETA or TETA or both in different percentages) and adjuvants, etc. We envision frequent cases of notification about the formulation of different components.

The practical meaning of (h)(2) needs further clarification because of its linkage with the issue of notification of approval of a product or one isolated component. Some questions on the interpretation of (h)(2) could be raised. How could a single substance notification be sufficient enough for the purposes of paragraphs (h)(6) and (h)(2)? Is the final product formulation the intent of the language in section (h)(2)? What is the FDA's legal basis to impede the use of an isolated, identical already approved component by all others but the original submitters?

Trade marks or patent rights could provide such protection in the case of a product but seldom on one substance alone. These are important questions that need further clarification.

CONCLUSION

At this moment this is the extent of our comments. We have respectfully requested an extension of the March 22 deadline since some of the documentation was distributed at the March 12 meeting, which only practically provided a week for commenting. We are hopeful that these comments are given full consideration and entered in the record.

We appreciate the Agency's willingness to share its thoughts and ideas on the matter, as well as the diligence of the staff present at the March 12 meeting to candidly respond to questions and share in the thought process leading to the preparation of the three draft documents. Without doubt, a lot of good work has been put into these drafts. We encourage the Agency to continue promoting this needed exchange.

Sincerely,

Sergio F. Galeano, Ph. D.
GEORGIA-PACIFIC CORPORATION

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